Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Note REV2017-17

Special Review of Sodium Chlorate: Proposed Decision for Consultation

(publié aussi en français)

28 June 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2017-XXE (print version)
H113-5/2017-XXE-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2017

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing sodium chlorate based on the decision taken by the European Commission in 2008 (European Commission, 2008a and 2008b) to not include the active substance chlorate in Annex I to Directive 91/414/EEC. The initiation of the special review for sodium chlorate was announced in December 2015 (Canada, 2015).

As required by subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern related to the pest control products containing sodium chlorate that prompted the special review. The aspect of concern for the active ingredient is relevant to human health.

The 2008 European Commission decision pertained to agricultural uses of sodium chlorate, magnesium chlorate and potassium chlorate. In Canada, there are no pesticide products containing magnesium chlorate or potassium chlorate registered. Sodium chlorate is registered as an industrial process fluid preservative in Canada. There are no agricultural uses of sodium chlorate currently registered in Canada.

2.0 Aspect of the Pest Control Product that Prompted the Special Review

Based on the review of the European decision (European Commission, 2008a and 2008b), the PMRA has identified the aspect of concern that prompted the special review of pest control products containing chlorate as:

- occupational mixer/loader/applicator exposure.

The European assessment concluded that information was insufficient to assess the leaching of a relevant metabolite to groundwater. However, no specific health or environmental concern was identified in the European assessment pertaining to leaching; therefore, this is not considered an aspect of concern for the special review.

The European decision pertains to occupational risk associated with the agricultural use of sodium chlorate; however, the PMRA special review has considered the aspect of concern in the context of the registered industrial process fluid use in Canada, as no agricultural uses are currently registered in Canada.

3.0 Uses of Sodium Chlorate in Canada

In Canada, sodium chlorate is used to control slime-forming microbes in pulp and paper process waters and recirculating cooling tower systems. This is achieved through the generation of chlorine dioxide in a closed system. As of 3 February 2017, there are six registered sodium chlorate containing products (Appendix I). All registered products containing sodium chlorate are included in this special review.

4.0 PMRA Evaluation of the Aspect of Concern that Prompted the Special Review

Following the initiation of the special review of sodium chlorate, the PMRA requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. No additional information was received.

In order to evaluate the aspect of concern for sodium chlorate, the PMRA has considered currently available relevant scientific information, which includes information from the European decision (European Commission, 2008c, 2008d and 2008e), information considered for the re-evaluation of sodium chlorate (Canada, 2008a and 2008b) and any other relevant information submitted since the re-evaluation.

No information related to the aspect of concern is identified in the Canadian incident report database.

4.1 PMRA Evaluation of the Aspect of Concern that Prompted the Special Review Assessment of the occupational mixer/loader/applicator exposure

As noted in Section 1.0, the European decision pertained to agricultural uses of various chlorates; however, there are no agricultural uses registered in Canada. However, occupational exposure to sodium chlorate may occur in Canadian industrial settings while loading the chemical into the chlorine dioxide generator.

The existing end-use product labels specify that the generator will be installed, adjusted and maintained by trained workers only. Current product labels specify personal protective equipment including single layer clothing, gloves, goggles and apron. The generator is a closed system with precursor chemicals piped in from storage tanks for reaction within the generator. Exposure to sodium chlorate may occur when changing the couplers of containers.

Dermal exposure is expected to be minimal based on use of a closed system and personal protective equipment. To assess the risk to workers from inhalation route, inhalation exposure was estimated for the maximum amount of sodium chlorate potentially handled. The assessment was based on an inhalation no-observed adverse effect level (NOAEL) of 30 mg/kg/day from a subchronic rat study. Under the current conditions of use (closed system, personal protective equipment), occupational dermal and inhalation exposure to sodium chlorate are not of concern (Canada 2008a). No further mitigation measures are proposed.

5.0 Proposed Special Review Decision for Sodium Chlorate

Evaluation of available scientific information related to the aspect of concern indicates that the registered products containing sodium chlorate are acceptable for continued registration considering the current Canadian use pattern. On this basis, the PMRA is proposing to confirm the current registration of products containing sodium chlorate for sale and use in Canada pursuant to subsection 21 (1) of the *Pest Control Products Act*.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

6.0 Next Steps

Before making a special review decision on sodium chlorate, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on sodium chlorate. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[1] "Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

Appendix I Registered Products Containing Sodium Chlorate as of 3 February 2017

Registration Number	Marketing class	Registrant Name Name	Product Name	Formulation	Guarantee
25141	Technical	Superior Plus Inc.	Technical Sodium Chlorate (solid)	Solid	99.9%
25143	Commercial	Superior Plus Inc.	Ercocide CP (solid)	Solid	99.9%
25632	Commercial	Solenis Canada ULC	Drew 3025 Biocide	Solution	25%
25800	Commercial	Superior Plus Inc.	Ercocide SP (liquid)	Solution	45.0%
29460	Technical	Akzo Nobel Pulp and Performance Chemicals Inc	EKA SC-R CRYSTAL	Solid	99.7%
29887	Commercial	Nalco Canada ULC	Purate	Solution	40%

References

Published Information

PMRA Number	Reference
1551538	Canada, 2008a. Pest Management Regulatory Agency. Proposed Re-evaluation Decision Sodium Chlorate and Sodium Chlorite. PRVD 2008-09
1585905	Canada, 2008b. Pest Management Regulatory Agency. Re-evaluation Decision Sodium Chlorate and Sodium Chlorite. RVD 2008-16
2709327	European Commission, 2008a. European Commission Decision: Concerning the non-inclusion of chlorate in Annex 1 to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. C(2008) 6587, November 10, 2008
2709328	European Commission, 2008b. Final report for the active substance chlorate, SANCO/196/08 – rev.2. June 4, 2008.
2709329	European Commission, 2008c. Draft assessment report (DAR) public version, Sodium Chlorate, Volume 1, January 2008
2709330	European Commission, 2008d. Draft assessment report (DAR) public version, Sodium Chlorate, Volume 3_B8, January 2008
2725907	European Commission, 2008e. Draft assessment report (DAR) public version, Sodium Chlorate, Volume 3_B6_part2, January 2008
2587309	Canada, 2015. Pest Management Regulatory Agency. Announcement for Initiation of Special Review, Sodium Chlorate.